

### **REMARKS**

Upon entry of the claim amendments, Claims 1-12 and 14 will be all the claims pending in the application.

#### **I. RESPONSE TO OBJECTION TO THE SPECIFICATION**

Referring to the Office Action Summary page, the examiner objects to the specification. At page 2 of the Office Action, the examiner states that “[t]he incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper.”

Applicants have closely reviewed the specification. Applicants are not aware of any incorporations by reference in the present specification, let alone any incorporations by reference of essential material. Applicants see no basis for the present objection to the specification.

If the present objection to the specification was not an oversight, and the examiner intends to maintain the present objection to the specification, counsel for Applicants kindly requests the examiner to contact the undersigned at the telephone number listed below in order to more clearly identify the language in the specification under objection.

Reconsideration and withdrawal of the present objection to the specification are requested.

#### **II. RESPONSE TO OBJECTIONS TO THE CLAIMS**

##### ***A. Claims 3 and 4***

Referring to the top of page 3 of the Office Action, Claims 3-4 are objected to under 37 C.F.R. § 1.75(c) as being a substantial duplicate of Claims 1 and 2.

Applicants respectfully disagree with the present objection. Claims 3 and 4 substantively differ in literal scope from Claims 1 and 2. For example, Claims 3 and 4 cover compositions which contain tranexamic acid and L-cysteine (in the case of Claim 4, within the specifically recited amounts), whereas component (i) of Claims 1 and 2 may be either tranexamic acid or a salt thereof, and component (ii) of Claims 1 and 2 may be L-cysteine or a salt thereof.

Reconsideration and withdrawal of the present objection are requested.

***B. Claims 12 and 13***

Claim 12 is objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 13. Also, Claim 14 is objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 15.

In response, Claims 13 and 15 have been canceled, thereby rendering moot the present objections to the claims.

Withdrawal of the present objections is requested.

**III. RESPONSE TO REJECTIONS UNDER 35 U.S.C. § 112**

***A. Claims 13 and 15***

Referring to the bottom of page 3 of the Office Action, Claims 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, because, according to the examiner, the specification, while being enabling for pigmentations caused by a drug, does not reasonably provide enablement for any pigmentation present on the skin.

In response, Claims 13 and 15 have been canceled, thereby rendering moot the present §112 rejection.

Withdrawal of the present §112 rejection is requested.

***B. Claims 9-10, 12, and 14***

Referring to page 4 of the Office Action, Claims 9-10, 12, and 14 are rejected under 35 U.S.C. § 112, as being indefinite.

According to the examiner, Claims 9 and 10 provide for the use of a composition, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

In response, Applicants have amended (i) Claim 9 to recite that the composition according to any one of Claims 1 to 8 is a composition for whitening skin and (ii) Claim 10 to

recite that the composition according to any one of claims 1 to 8 is a composition for preventing and/or treating pigmentations.

Withdrawal of the present §112 rejection, as it applies to Claims 9 and 10, is requested.

Regarding Claims 12 and 14, the examiner requests clarification because the examiner asserts that it is unclear what applicant is intending to whiten. The examiner states that she “is interpreting these claims to be a method of whitening the skin.

In response, Applicants have amended the preambles of Claims 12 and 14 to recite a method of whitening skin.

Withdrawal of the present §112 rejection, as it applies to Claims 12 and 14, is requested.

#### **IV. RESPONSE TO REJECTION UNDER 35 U.S.C. § 101**

Referring to the bottom of page 4 of the Office Action, Claims 9 and 10 are rejected under 35 U.S.C. § 101, because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process.

In response, Applicants have amended (i) Claim 9 to recite that the composition according to any one of Claims 1 to 8 is a composition for whitening skin and (ii) Claim 10 to recite that the composition according to any one of claims 1 to 8 is a composition for preventing and/or treating pigmentations.

Withdrawal of the present §101 rejection is requested.

#### **V. RESPONSE TO REJECTION UNDER 35 U.S.C. § 102**

Referring to pages 5 and 6 of the Office Action, Claims 1-10 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2001/0012853 (“Bissett”).

Applicants respectfully traverse.

For anticipation under 35 U.S.C. § 102, the identical invention must be shown in as complete detail as is contained in the claim. With respect to each of presently rejected Claims

1-10 and 12-15, Bissett does not disclose the claimed subject matter as is required for an anticipation under §102.

First, Bissett does not disclose an actual embodiment or working example specifically containing the combination of (i) tranexamic acid or a salt thereof and (ii) L-cysteine or a salt thereof.

Second, Bissett's mentions of "N-acetyl-L-cysteine and derivatives thereof" at paragraph [0048], "ascorbic acid and derivatives such as ascorbyl phosphate salts, placental extract, and the like" later at paragraph [0048], and "tranexamic acid" at paragraph [0049], are the only mentions related thereto in the entirety of its disclosure, and they are disconnectedly mentioned as optional components of the skin-regulating compositions of Bissett ("The skin regulating compositions of the present invention may optionally comprise additional skin actives." See the first sentence in paragraph [0048]. "Other conventional skin care product additives may also be included in the compositions of the present invention." See the first sentence in paragraph [0049].). Nowhere does Bissett mention the exact compositions recited in the presently rejected claims.

Still further, the asserted position on anticipation with respect to Claims 2, 4, 6, and 8, each of which recites administrating amounts, is improper. The case law relied upon is relevant to a §103 obviousness rejection. Nowhere does Bissett mention the administrating amounts recited in Claims 2, 4, 6, and 8. The present §102 anticipation rejection, as it applies to Claims 2, 4, 6, and 8, is groundless.

Still even further, Applicants present the following argument to traverse the present rejection, as it applies to Claims 3-4 and 7-8. Unlike Claims 1-2 and 5-6, which recite "L-cysteine or a salt thereof," Claims 3-4 and 7-8 recite L-cysteine. Bissett does not disclose L-cysteine. The only disclosure contained in Bissett concerning cysteine is the disclosure at paragraph [0048] of "N-acetyl-L-cysteine and derivatives thereof." N-acetyl-L-cysteine is itself a derivative of L-cysteine. Thus, the disclosure at paragraph [0048] of "N-acetyl-L-cysteine and derivatives thereof" does not disclose the L-cysteine of Claims 3-4 and 7-8.

Reconsideration and withdrawal of the present §102 rejection are requested.

**VI. RESPONSE TO REJECTION UNDER 35 U.S.C. § 102**

Referring to pages 6 and 7 of the Office Action, Claims 1-10 and 12-13 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0137077 (“Ancira”).

Applicants respectfully traverse.

With respect to each of presently rejected Claims 1-10 and 12-13, Ancira does not disclose the claimed subject matter as is required for an anticipation under §102, for essentially the same reasons as discussed at Section V above in connection with the Bissett reference. Like Bissett, Ancira does not disclose an actual embodiment or working example specifically containing the combination of (i) tranexamic acid or a salt thereof and (ii) L-cysteine or a salt thereof. Further, similar to Bissett, Ancira only mentions tranexamic acid once (at paragraph [0034]), wherein it is identified as an optional melanin inhibitor along with a long list of other melanin inhibitors. Thus, nowhere does Ancira mention the identical compositions recited in the presently rejected claims.

Likewise, the present §102 anticipation rejection as it specifically applies to Claims 2, 4, 6, and 8 is groundless. The examiner again relies on case law relevant to a §103 obviousness rejection to meet the administering amounts recited in Claims 2, 4, 6, and 8. Nowhere does Ancira mention the administering amounts recited in Claims 2, 4, 6, and 8.

Reconsideration and withdrawal of the present §102 rejection are requested.

**VII. RESPONSE TO REJECTION UNDER 35 U.S.C. § 102**

Referring to page 7 of the Office Action, Claims 1-4 and 11 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,974,833 (“Rath”).

Applicants respectfully traverse.

Present Claims 1 and 2 recite “L-cysteine or a salt thereof.” Present Claims 3 and 4 recite “L-cysteine.” The remainder of the independent claims recite various combinations of “tranexamic acid” (or a salt thereof) and “L-cysteine” or a salt thereof.

Rath does not disclose L-cysteine (or a salt thereof). The only disclosures contained in Rath concerning cysteine are the disclosures at column 5, line 3, and Table 1 of “N-acetyl cysteine.” N-acetyl-cysteine is itself a derivative of L-cysteine. The disclosure of “N-acetyl cysteine” in Rath does not disclose the presently recite L-cysteine (or a salt thereof).

Reconsideration and withdrawal of the present §102 rejection are requested.

### **VIII. CONCLUSION**

Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the examiner feels may be best resolved through a personal or telephone interview, the examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

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CUSTOMER NUMBER

/L. Raul Tamayo/

Raul Tamayo  
Registration No. 47,125

Date: March 5, 2007